



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,856	07/15/2003	Paul DiTullio	21578-017	7749

30623 7590 09/28/2004

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,856

Applicant(s)

DITULLIO ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1644

1. Claims 1-18 are under consideration.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
3. Claims 1-4,8-10,13,14,17,18 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by Briskin et al. (US 2002/0090657) (as evidenced by Gallatin et al., Green and Rotter et al).

Briskin et al. teach the production of antiBonzo antibodies via immunization of C57BL6 mice with pre-B lymphoma L1.2 cells transfected with heterologous nucleic acids encoding the cell surface protein Bonzo (see page 20, sections [0166] to [0168]) wherein Bonzo is expressed on the surface of said cells(page 23, section [0190]). Gallatin et al. discloses that the L1.2 (aka L1-2) lymphoma cell is derived from C57L mice (see Table 1). Green discloses that C57BL6 mice and C57L mice are both H-2^b positive (see abstract, second paragraph). H-2 is the mouse MHC loci. Therefore, it is an inherent property of the method taught by Briskin et al. that the transfected cells and recipient are syngeneic (eg. matched) at the MHC loci. It is an inherent property of the L1.2 cell line that it an immortalized bone marrow cell (see Rotter et al., first paragraph). Thus L1.2 is not an embryonic cell. L1.2 is a differentiated cell (eg. pre-B lymphoma).
4. Claims 1-7,12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon et al. (US Patent 6,075,125).

Art Unit: 1644

Bacon et al. teach that chicken cells transfected with a nucleic acid encoding a heterologous protein expressed on the cell surface can be used to immunize chickens for the production of antibodies (see abstract and columns 6,7 and 10, second paragraph). Bacon et al. disclose that the recipient chicken and transfected cell should be syngeneic at the chicken MHC loci (eg. they are of the same B haplotype, see column 6, first complete paragraph and column 1, third paragraph). The cells to be transfected can be immortal, derived from bone marrow, derived from spleen (column 6, first complete paragraph) or derived from fibroblasts of an adult animal (see last sentence, column 6, continued on column 7). The aforementioned fibroblasts from an adult animal are not an embryonic cell and is a differentiated cell. The art recognizes that bone marrow cells contain undifferentiated stem cells.

5. Claims 1-3,8-10 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by Rybak et al. (US Patent 6,395,276).

Rybak et al. teach production of monoclonal antibodies via immunization with autologous cells transfected with human B cell antigens wherein the transfected cells are autologous with the immunized animal (AKA MHC matched)(see column 9, last paragraph continue on next page). Rybak et al. disclose use of mice for the production of monoclonal antibodies (see column 9, fourth paragraph).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3,7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rybak et al. (US Patent 6,395,276) in view of McCormack et al. (US Patent 5,472,868).


Rybak et al. teach production of monoclonal antibodies via immunization with autologous cells transfected with human B cell antigens wherein the transfected cells are autologous with the immunized animal (AKA MHC matched)(see column 9, last paragraph continue on next page). Rybak et al. disclose use of mice for the production of monoclonal antibodies (see column 9, fourth paragraph). Rybak et al. do not teach use of rabbits in the claimed method. McCormack et al. disclose use of rabbits for the production of monoclonal antibodies (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Rybak et al. teach production of monoclonal antibodies via immunization with autologous cells transfected with human B cell antigens wherein the transfected cells are autologous with the immunized animal whilst McCormack et al. disclose use of rabbits for the production of monoclonal antibodies. One of ordinary skill in the art would have been motivated to do the aforementioned because McCormack et al. teach the advantages of using rabbits to produce monoclonal antibodies (see column 1, penultimate paragraph).

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1644

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800-1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644